510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: K062194

APR 11 2007

Submitter:

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- **Contact Person:**

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- **Date Prepared:**

July 14, 2006

Name of the device:

- **Trade/Proprietary Name:** HYPERVISOR VI Central Monitoring System
- **Common Name:** Central Monitoring System
- **Classification**

21 CFR 870.2300	Cardiac monitor (including cardiotachometer and rate alarm)	Class II
21 CFR 870.1130	Non-Invasive blood pressure measurement System	Class II
21 CFR 870.1110	Blood pressure computer	Class II
21 CFR 880.2910	Clinical Electronic Thermometers – Temperature Monitor with Probe	Class II
21 CFR 870.2700	Oximeter, Pulse	Class II
21 CFR 868.1400	Carbon Dioxide Gas Analyzer	Class II
21 CFR 868.1720	Oxygen Gas Analyzer	Class II

Legally Marketed Predicate Device:

K011093 Agilent Technologies Information Center (AIC) Software

Description:

Central Monitoring System is a kind of medical information system widely applied in clinical monitoring, whose operation requires specific hardware environment such as a PC platform, the PC and Operation System is dedicated. Depending on the specific hardware platform, the Central Monitor System constitutes a monitoring network system together with software, the Operation System and work together with bedside monitors. It can collect, and export the monitoring information of the patient transferred via network from the bedside monitor. It can also display and export the integrated information from bedside monitors so as to free-up doctors from clinical monitoring work and create centralized monitoring management.

The HYPERVISOR VI Central Monitoring System is a medical information system. This System includes a high-performance PC hardware system, the application software and Windows operation system (Windows XP). Through applying Mindray specified protocol, the Central Monitoring System obtains physiological information from cleared bedside monitors manufactured by Mindray, includes: PM-8000 Express, PM-9000 Express and VS-800.

The Central Monitoring System can maximally support the simultaneous networking of 32 bedside monitors. Also, TCP/IP protocol is applied to ensure reliable transmission of network data.

The Central Monitoring System offers centralized display of physiological information of many patients who are currently monitored simultaneously. The software can support two displays simultaneously, and can display information from up to 16 bedside monitors on a display and 32 bedside monitors on two displays simultaneously. And if any of the bedside monitors gives off alarm, prompt information will be immediately displayed by means of audible /words for medical personnel's attention.

The physiological waveforms displayed on the central monitoring system include to: ECG waveforms, RESP waveforms, CO_2 waveforms, PLETH waveforms, IBP waveforms, and AG waveforms. The physiological parameters displayed on the central monitoring system include: HR, RR, SpO_2, PR, SYS, DIA, MEAN, TEMP, CO_2, AwRR.

Central Monitoring System makes an announcement for the physiological parameters based on the bedside monitor. The software also performs notification directly for alarms from the bedside monitor and triggers technical alarms for the error and failure of itself. Moreover database technology is applied to store these alarm events for the convenience of doctor's review and analysis.

Statement of intended Use:

The Central Monitoring System is intended to conduct centralized monitoring of adult, pediatric and neonatal vital sign information from multiple monitors in hospitals or medical institutions, the monitoring parameters include ECG, NIBP, SpO_2, PR, RESP, IBP, TEMP, CO_2 and AG. It is not intended for home use.

Comparison of Technological Characteristics:

The HYPERVISOR VI Central Monitoring System is substantially equivalent to currently marketed predicate device. Both HYPERVISOR VI Central Monitoring System and the M3150 predicate device free-up doctors from clinical monitoring work and create centralized monitoring management.

The notable difference between the technical specifications of the HYPERVISOR VI and M3150 is shown as following:

1. M3150 predicate can be used for ST segment and arrhythmia analysis, while the Central Monitoring System can not.
2. M3150 can be used for Telemetry and wireless monitoring, while Central Monitoring System can not;
3. The PC basic requirement is different, such as the operation system for Central Monitoring System is Windows XP professional, while M3150 is Windows NT4.0; the host CPU of Central Monitoring System is PIV 2.0 G, while the M3150 is PII 400+MHz;
4. For Central Monitoring System, the maximum number of connecting bedside monitors is 32, while for M3150, the number is 16.

Conclusion:

The conclusions drawn from testing and validation of the HYPERVISOR VI Central Monitoring System demonstrates that the device is as safe, as effective, and performs as well as the legally marketed predicate device, the M3150 Information Center (K#011093, by Agilent Co., Ltd).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2007

Shenzhen Mindray Bio-Medical Electronics Co. Ltd.
c/o Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K062194
Trade/Device Name: Hypervisor VI Central Monitoring System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: MHX
Dated: March 9, 2007
Received: March 12, 2007

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

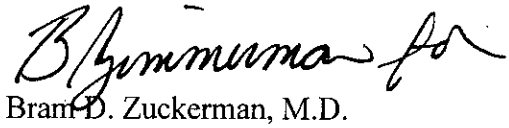
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #E

510(k) Number (if known): K062194 Page 1 of 1

Device Name: HYPERVISOR VI Central Monitoring System

Indications For Use:

The Central Monitoring System is intended to conduct centralized monitoring of adult, pediatric and neonatal vital sign information from multiple monitors in hospitals or medical institutions, the monitoring parameters include ECG, NIBP, SpO_2, PR, RESP, IBP, TEMP, CO_2 and AG. It is not intended for home use.

Prescription Use X (Per 21 CFR 801 Subpart D)

Over-The Counter Use _____ OR (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062194